

Study official title: Partnership with the Community to Improve the Well-being of People with Mild Cognitive Impairment (MCI)/Early Dementia and their Caregivers with Music Intervention: an Effectiveness-Implementation Cluster Randomized Clinical Hybrid Trial

Principal Investigator: Daphne Cheung

Co-Principal investigator: Claudia Lai

Co-Investigators: Lily Ho, Daniel Lai

Version: 1.0

Date: 14-March-2018

Partnership with the Community to Improve the Well-being of People with Mild Cognitive Impairment (MCI)/Early Dementia and their Caregivers with Music Intervention: an Effectiveness-Implementation Cluster Randomized Clinical Hybrid Trial

Daphne Cheung (PI), Claudia Lai (Co-PI), Lily Ho, Daniel Lai

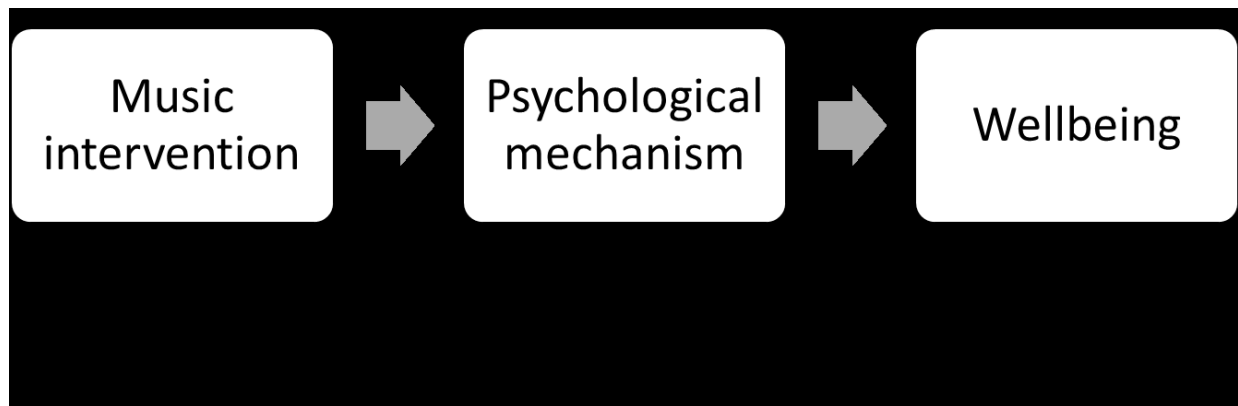
BACKGROUND

Dementia is a neurodegenerative disorder and it can adversely affect patient's cognitive, behavioural, social and emotional functioning. Its prevalence will increase continuously because of the increase in aging population and it is predicted that around 333,000 people in Hong Kong (equivalent to 11% population aged 60 or above) will suffer from dementia in year 2039 (Legislative Council of the Hong Kong SAR, 2017; Prince et al., 2013; Yu et al., 2012). The gradual functional decline, communication difficulties, the behavioural symptoms associated with cognitive impairment, may affect the relationships with the family members and the wellbeing (Wadham, Simpson, Rust, & Murray, 2016). A latest Cochrane Review commented that music-based intervention may be helpful to improve emotional wellbeing and quality of life according to some limited evidences, as well as depressive symptoms, although future studies with larger sample sizes and more rigorous research design are suggested (van der Steen et al., 2017).

In 2014 – 2016, our team has modified a music-with-movement intervention designed for nursing home residents with moderate dementia (Cheung, Lai, Wong, & Leung, 2018), into a protocol specified for caregiver-delivered home-based intervention to promote the psychosocial wellbeing of people with early dementia in Hong Kong (Lai, Lai, Ho, Wong, & Cheung, 2016). We found that the dyadic music-with-movement intervention yielded significant reduction on anxiety levels of people with early dementia as compared to control group (Lai et al., 2016). Similar, Särkämö and colleagues (2017) also found that caregiver-implemented music intervention group have reduced depression of people with early dementia and reduced caregiver burden. With the strong evidence that music intervention is useful in improving the wellbeing of people with early dementia and their family caregiver, it is essential to disseminate the culture-appropriated and validated intervention for promoting health and evaluate its effectiveness in real-practice setting by implementation research.

This research is anchored by a conceptual framework of leisure and subjective wellbeing (Newman, Tay, & Diener, 2014). This framework explained that through participating in activities outside the obligated works (either paid or unpaid) that is subjectively regarded as leisure, would lead to an improvement of well-being through five psychological mechanisms, namely detachment-relaxation, autonomy, mastery, meaning and affiliation (Newman et al., 2014) (see figure 1). Caregivers and care-recipients are found relaxed after participating in music intervention because they are temporary detached from the everyday caregiving chaos (Roland & Chappell, 2015). Participating in an intervention designed by the participants themselves would increase their sense of autonomy and mastery (Ryan, Patrick, Deci, & Williams, 2008). During the dyadic music intervention, the caregivers and people with MCI/early dementia would design their activities within the music-with-movement framework after instruction of music therapist that allow them to exercise their choices based on their music preference. Through the interaction in the dyadic intervention, it has been found that through participating in dyadic music intervention, people with dementia and their caregivers have improved in relationship and social inclusiveness (Osman, Tischler, & Schneider, 2016; Roland & Chappell, 2015). Caregivers would feel their competence or mastery in the skills when leading music intervention (Van't Leven et al., 2013). Staff and caregivers reported that activities that address the psychological needs, provide enjoyment, value individuality, reinforce a sense of identity and belonging are meaningful to people with dementia (Harmer & Orrell, 2008; Sixsmith & Gibson, 2007). Therefore, we hypothesized that dyadic music-with-movement intervention would improve the subjective wellbeing of both the people with MCI/early dementia and their caregiver, if there are relevant implementation strategies to increase the ease of uptake of the intervention. For example, stress of caregivers could be relieved by successful music intervention.

Fig.1 Conceptual Framework



When the aim is to maximize the uptake of the intervention in the real-life settings as a routine, we have to examine the influence of contextual factors on implementation. Hence, this study have three main objectives:

1. To test the effectiveness of the dyadic music-with-movement intervention on wellbeing of people with MCI/early dementia, and of their caregivers in real-life settings;
2. To conduct a process evaluation of the effectiveness-implementation study by gathering information on the implementation process; and
3. To validate and extend the applicability of “Leisure & Wellbeing” conceptual framework to the dyads.

In this project, one of the implementation strategies to maximize the uptake of the music intervention by the dyads, is to train a team volunteers to support the caregivers and people with MCI/early dementia, which is a unique group of population. There is a general lack of knowledge and inappropriate attitude towards dementia or Alzheimer’s disease worldwide (Cahill, Pierce, Werner, Darley, & Bobersky, 2015; McParland, Devine, Innes, & Gayle, 2012; Woo, 2013). In Hong Kong, it was reported that university students majoring in medicine, nursing, occupational therapy and social work showed inadequate knowledge towards this group of patients (Kwok, Lam, Yip, & Ho, 2011). By providing training for volunteers to support participating dyads, it would be able to provide a better understanding on dementia and create a supportive community for dementia. Therefore, we will explore the changes in the following outcomes of the volunteers:

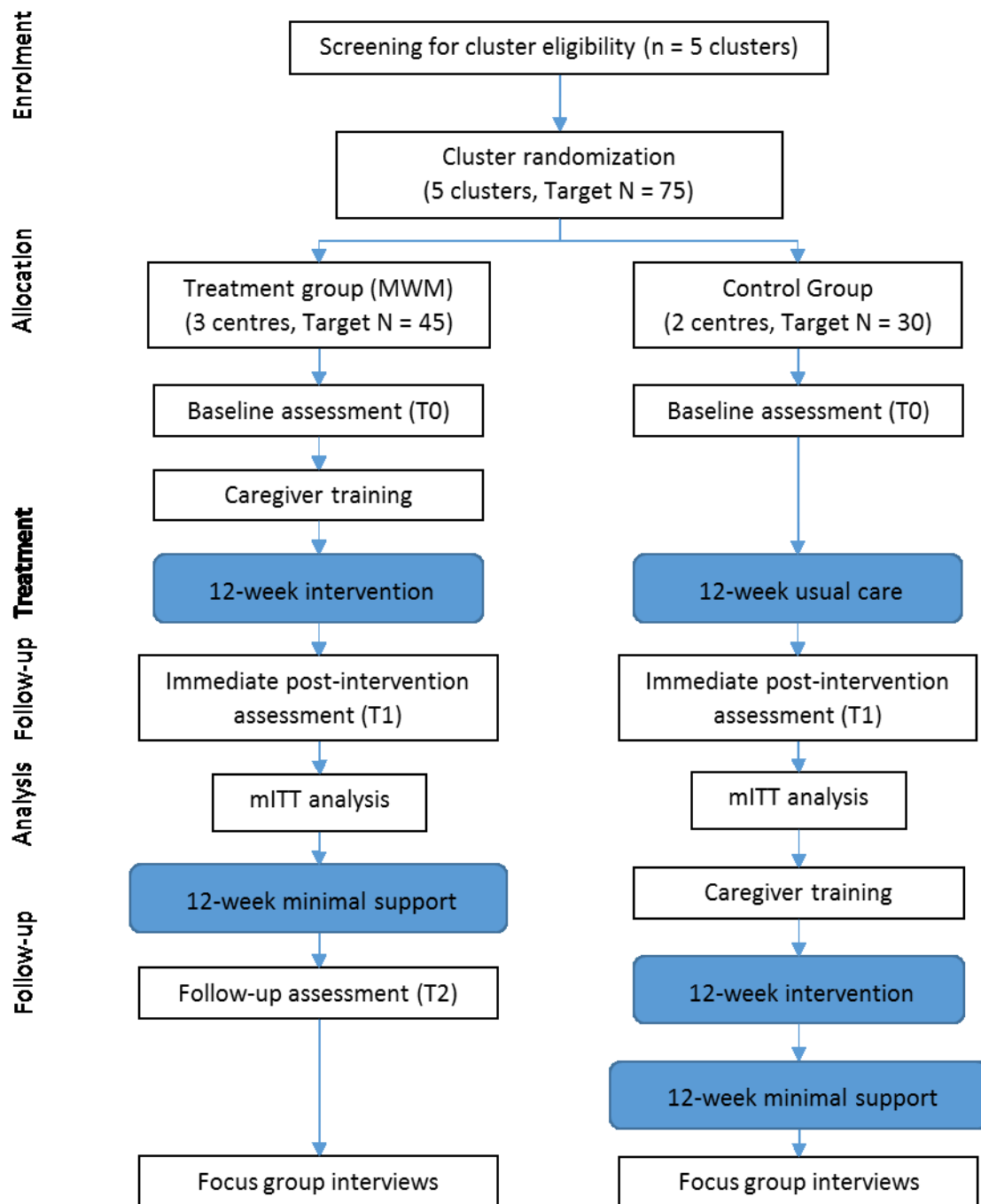
4. To examine the change of knowledge and attitudes towards dementia of the volunteers before and after participating in the project; and
5. To examine the change of satisfaction and motivation to volunteering before and after participating in the project.

METHODS

This is a 3-month multicenter, cluster randomized controlled effectiveness-implementation hybrid trial with follow-up at month 6, involving 75 dyads from 5 community social services organizations in Hong Kong (Flow chart in Fig. 2). The mixed method design comprises the quantitative assessment with validated outcome measures and qualitative evaluation of the implementation strategies effectiveness by interviews of the dyads.

The design of effectiveness-implementation hybrid approach allows us to assess the effectiveness of both an intervention and the implementation strategies (Curran, Bauer, Mittman, Pyne, & Stetler, 2012). Cluster RCT design allows us to evaluate the effectiveness of the intervention on the dyadic outcomes of people with MCI/early dementia and their caregivers, which will be assessed with validated instruments at different time-points. The successfulness of the implementation strategies as process evaluation, will be appraised with both quantitative and qualitative assessments on all stakeholders of this project (i.e. staff, volunteers, caregivers, and people with MCI/cognitive impairment).

Fig. 2 Flow chart of the study



Settings and target population

Organizations providing social services to people with MCI/early dementia, and/or the families with people with MCI/early dementia in Hong Kong will be included. We will recruit the organizations by purposive sampling method through personal networks. These organizations are providing social services to either the older adults or family caregivers in Hong Kong. Each organization will be regarded as a cluster. Selection criteria of target population is as below:

Inclusion criteria:

- People with MCI/early dementia (Global Deterioration Scale Grade 3 or 4 respectively) who are living at home; aged 60 or above; in a stable medical condition; and able to communicate in Cantonese; and

- Family caregiver who is willing to participate the training and deliver the trained intervention at home three times per week.

Exclusion criteria:

- Either people with MCI/early dementia or their family caregivers with critical medical or psychiatric illnesses; and
- Either people with MCI/early dementia or their family caregivers received music intervention within six months upon recruitment.

Sample size

There was a significant interaction effect (time x group) was found on anxiety level of PWeD, with the effect size of Cohen's $d = 0.361$ (Lai et al., 2016). With reference to the effect size, power = 0.8, $\alpha = 0.05$, number of measurement (T0, T1), and the attrition rate of 16.7% (Lai et al., 2016), and assumed the cluster design effect ICC = 0.01, the total sample size required = 86. The Foundation, which supports this project is only willing to support 75 families, which may be the limitation in this study.

The conventional focus group size ranges from 5 – 12 participants (Krueger & Casey, 2015). Regarding to the sample size of the staff members, volunteers, caregivers and people with MCI/early dementia to be interviewed, the details are tabulated as below:

	Number	Approach	Venue
Staff	2 from each organization	Two focus group interviews will be held for treatment group and control group separately post-intervention.	@ PolyU
Volunteers	8 from each organization	5 focus group interviews will be held separately. Each group consists of 8 volunteers serving for the same organization.	@ Corresponding centres
Caregivers & People with MCI/early dementia	4 dyads from each organization	5 focus group interviews will be held separately. Each group consists of 4 dyads recruited by the same organization.	@ Corresponding centres.

Randomization

Organization are cluster randomized to intervention group or wait-list controlled group. The implementation strategies may be optimized during the process. Hence, the participating center staff and participating dyads cannot be completely blinded to group allocation, although cluster-randomized control design is more preferable to reduce the potential contamination between groups. However, the trained assessors will be blinded to the group allocation.

Before randomization, all participating centers will be informed about the study design, the aims and the content of the intervention. Each center will be randomized to intervention or control group using the random number generated by a computer. Participating dyads will follow the group allocation of their corresponding centers.

Dyadic music-with-movement music intervention

A validated 12-week MWM intervention will be adopted in this project. The MWM intervention will be delivered by the CG at home three times a week for 20 – 30 minutes each time. With input from organization project coordinators, the intervention protocol is modified by including four sessions of MWM taken place in the corresponding centre (at Week 1, 3, 7 and 12), and sending trained volunteers (instead of staff members) to visit the family for three times throughout the intervention period (at Week 2, 5, and 9), for enhancing the sustainability and fidelity. After 12-week intervention, i.e. starting of 12-week minimal support phase, trained volunteers will visit these families monthly.

During the intervention, CG and people with MCI/early dementia will listen to their preferred music and move their body parts. CG will also be the facilitator to encourage his/her family members to engage in the music activities. The activities may include dancing, playing with musical instruments, etc. (See Appendix A for details)

Control condition

The control group will receive care as usual, during the trial. The usual care includes social support to either the CG or the people with MCI/early dementia to motivate control group to continue participating, they will receive the same intervention, training and support from volunteer after the data collection at month 3.

Training of centre staff (trainer) and volunteer (ambassador)

Volunteers will be trained as the assistants of centre staff to visit the home of the participating families. The training package for the staff and volunteers is modified based on our last project (Lai 2015) by trimming 2 sessions to cater the busy work of staff in order to increase their commitment. The project team will teach the staffs and volunteers about the techniques in music-with-movement intervention for people with MCI/early dementia, as well as being a trainer of caregivers to deliver the intervention at home. The training programme for staff is 8 hours in total (2 hours x 4 sessions), while there are additional 2 hours for volunteers to introduce the basic knowledge of cognitive impairment before training with staff.

Training of CG

Caregivers will be trained for 8 hours (2 hours x 4 sessions). The training package is slightly modified from the protocol of the last project but trimming down from 6 sessions. Without affecting the dosage of the training, an e-book (developed from the last project), which contains most of the necessary skills will be introduced.

Implementation strategies

The implementation strategies are developed based on the experience of our previous randomized controlled trial. The strategies are developed according to the feedback from the CGs and the staff members of the participating centers of previous studies. Our strategies focus on empowering and partnership with local community service centers to adopt the intervention in their practice, and empowering and supporting the family caregivers to deliver the intervention at home. The details about the implementation strategies, please refer to Appendix B.

Data collection

Demographic characteristics and music preference at baseline

The following demographic and music preference will be collected at baseline.

	People with MCI/early dementia	CG	Volunteer	Staff
Age	√	√	√	√
Gender	√	√	√	√
Education	√	√	√	√
Living arrangement	√	√		
Marital status	√	√		
Relationship with the person with MCI/early dementia		√		
Medical history	√	√		
(Past / Current) Occupation	√	√	√	√
Caregiving experience		√		
Use of antipsychotic drugs	√	√		
Cognitive functions (MoCA)	√			
Music preference	√	√		
Years of working experience in dementia care			√	√

Effectiveness measure (quantitative)

The outcome measures will be measured at baseline (T0), at 3-month post randomization (T1), and at 6-month post randomization (T2; in the treatment group only because of funding limitation). For details, please see Appendix C.

1. On people with MCI/early dementia
 - Rating Anxiety in Dementia (RAID) (Shankar, Walker, Frost, & Orrell, 1999) (Chinese version -- Cheung, Lai, Leung, 2017)
 - Cornell scale for depression in dementia (CSDD) (Alexopoulos, Abrams, Young, & Shamoian, 1988a, 1988b) (Chinese version -- (Lin & Wang, 2008))
2. On CG
 - Perceived Stress Scale 10 (PSS-10) (Cohen, Kamarck, & Mermelstein, 1983) (Chinese version --(Leung, Lam, & Chan, 2010))
 - Positive Aspects of Caregiving measure (Tarlow et al., 2004) (Chinese version -- (Lou, Lau, & Cheung, 2015))
 - Heart Rate Variability measuring with Polar OH1 optical heart rate monitor armband (on caregivers with high stress at baseline only, i.e. PSS total score over 24)
3. Dyadic relationship
 - Quality of the Caregiver-Care Recipient Relationship (Lawrence, Tennstedt, & Assmann, 1998)
4. On volunteers
 - Volunteer Satisfaction Index (VSI) (Galindo-Kuhn & Guzley, 2002) (Chinese version -- (Wong, Chui, & Kwok, 2011))
 - Volunteer Functions Inventory (VFI) (Clary et al., 1998) (Chinese version -- (Wu, Lo, & Liu, 2009))
 - Dementia Attitudes Scale (DAS) (O'Connor & McFadden, 2010) (Chinese version -- (Xia, 2014))
 - Alzheimer's Disease Knowledge Scale (Carpenter, Balsis, Otilingam, Hanson, & Gatz, 2009) (Chinese version --(Xia, 2014))

There are 3 time points for data collections, baseline (T0), immediate post-intervention (T1) and 3-month post-intervention (T2). For dyads randomized into intervention arm, assessments will be performed in all 3 time points. For dyads randomized into control arm, assessments will only performed at T0 and T1, i.e. no data would be collected among dyads randomized into control arm after the end of 12-week usual care.

Process evaluation Indicators of effective implementation strategies (mixed-method)

Upon the completion of the intervention, each stakeholders of this project will be interviewed about the implementation strategies in the following aspects:

Implementation outcomes	Target groups	Method of data collection
1. Fidelity	Caregiver	Self-report competency Focus group interview of volunteers
2. Dose	Dyad	Log book
3. Acceptability	Dyad, staff and organization	Focus group interviews of dyads and staffs
4. Adoption <i>Staff intention to adopt as routine intervention</i>	Organization	Focus group interviews of staff
5. Appropriateness <i>Perceived relevance of the intervention</i>	Organization	Focus group interviews of staff
6. Feasibility	Dyads, organization	Focus group interviews of dyads and staff
7. Sustainability	Dyads, organization	3 months post-intervention assessment

The semi-structure interview questions can be seen in Appendix D.

Conceptual model validation (qualitative)

To strengthen our understandings on how “Leisure and Wellbeing” conceptual framework able to explain the improvement of wellbeing of the dyad, semi-structured interviews will be conducted with five focus groups of dyads regarding the MWM music interventions after completion of the intervention. The research team will facilitate the group discussions by sequencing questions from the general to the specific (Kruger and Casey, 2015). The sequencing will be guided by the bottom up approach of the “Leisure and Wellbeing” conceptual framework, which divide the interviews into different domains:

1. Opening domain: Experiences of music intervention as structural activities outside obligated work time and subjective engagement to leisure
2. Domain I: Detachment-recovery
3. Domain II: Autonomy
4. Domain III: Mastery
5. Domain IV: Meaning
6. Domain V: Affiliation
7. Concluding domain: Satisfaction and wellbeing

The semi-structure interview questions can be seen in Appendix D.

Data management and analyses

A project coordinator will be responsible to assist the principal investigator to oversee the implementation of the programme and manage the data collected by trained research assistants. Each person with MCI/early dementia participant will be assigned an identity code. All the questionnaires or the database would not consist of the name of the participants. Instead, an identifier will be assigned to each participants. Data will be stored in a computer locked with password. Raw data in paper form will be stored in a locked cabinet in a research office with 24 hours security monitoring. Only the research team can access the information. All the data will be permanently discarded three years after the completion of the trial.

Demographics and clinical characteristics between intervention and control group will be compared at baseline using Chi-square test for categorical variables, and independent t-test for continuous data if they are normally distributed, or Mann-Whitney U-test of the data are not normally distributed.

In addition to PSS-10 collected among caregivers, heart rate variability (HRV) can provide physiological evidence on changes in stress. Stress can modulate both sympathetic and parasympathetic cardiac control, i.e. HRV varies with stress level and it can be used as indicator of stress (Berntson & Cacioppo, 2004). High frequency (HF) HRV is regulated by parasympathetic control while low frequency (LF) HRV is regulated by both sympathetic and parasympathetic action (McDuff, Gontarek, & Picard, 2014). Nowadays HRV can be estimated by measurement of pulse rate variability using photoplethysmograms function implanted in smartphone or smartwatch (Peng, Zhou, Lin, & Zhang, 2015). Artefacts of HRV data will be corrected by Kubios HRV Premium 3.0 (Biosignal Analysis and Medical Imaging Group, Kuopio, Finland) before statistical analysis (Darragh, Booth, Koschwanez, Sollers, & Broadbent, 2013; Tarvainen, Niskanen, Lipponen, Ranta-Aho, & Karjalainen, 2014) because measurement of HRV by PPG is affected by environment and motion more easily than conventional ECG method hence motion artefacts are produced more easily by PPG-measured HRV signals (Kranjec, Beguš, Geršak, & Drnovšek, 2014).

There are several different parameters extracted from HRV signals. LF parameters of HRV would be analyzed since previous review reported that LF parameters are more prone to be affected by stress (Reyes del Paso, Langewitz, Mulder, Roon, & Duschek, 2013). Therefore mean and SD of RR intervals, ratio between LF and HF band powers, powers and peaks of VLF, LF and HF would be analyzed (Tarvainen et al., 2014). These parameters will be analyzed in the way similar to other continuous variables (Repeated ANCOVA).

For the quantitative analysis, modified intention-to-treat analysis approach will be adopted for evaluating the clinical effectiveness of the intervention, i.e. subjects in intervention arm without receiving first session of music intervention will

be excluded from analysis (Montedori et al., 2011). Missing data will be imputed before the analysis. Repeated ANCOVA will be used to evaluate the change of the outcome variables over time. The intraclass correlation coefficient will be calculated to assess the proportion of the total variance in data between included clusters.

The interviews will be audio-recorded and transcribed verbatim. Directed content analysis will be employed to analyze the focus group interview data to examine the implementation outcomes. For model validation, transcribed verbatim will be analyzed under the approach of directed content analysis (Hsieh & Shannon, 2005) under the pre-determined “Leisure & Wellbeing” conceptual framework. The goal of directed content analysis is to validate or extend conceptually a theoretical framework. This contributes to our objective to investigate how the “Leisure & Wellbeing” conceptual framework is applicable to the MCI dyad. By reading the transcriptions line-by-line, the research team will highlight the text that on first impression appears to represent the constructs in the “Leisure & Wellbeing” conceptual framework. The research team will further identify key concepts as initial coding categories using the “Leisure & Wellbeing” conceptual framework. Aftermath, operational definition for each category will be determined using the same conceptual framework. Throughout the whole analysis, team members will review on the developed codes and categories. The relationships between generated categories and sub-categories will be further explored in order to explain the improved wellbeing of the dyad. Whenever there are data that cannot be coded under the framework, these data will be determined if they represent a new category which is not included in the framework. This allows the research team to capture any phenomenon which may not be explained by the conceptual framework and to offer additional explanation the effect of MWM on the wellbeing of the dyad. This is deemed important to capture the particularities of MCI dyad and assists in the translation of a general conceptual framework to be utilized by MCI dyad.

Ethical consideration

This study will be registered in clinicaltrials.gov. Ethical approval from the University and corresponding organizations will be sought. Information sheet will be given to the staff members and volunteers who will be involved in this study, caregivers and PWeD or people with MCI. Verbal and written informed consent will be obtained from the staff, volunteers, caregivers and PWeD or MCI participants after explaining the purpose and procedures of the research. Continuous verbal consent will be obtained from the participating PWeD or people with MCI when the research assistant conduct data collection on them. Caregivers, volunteers and centre staffs are advised not to implement the music intervention to the PWeD or people with MCI if they refused.

Center social worker will support the staff, volunteers, caregivers and PWeD or people with MCI when there is emotional upset arise during the trial. However, based on our previous experience, the intervention is safe and the possibility of inducing any emotional distress on the participants is low.

Video will be captured during the music intervention delivering at home on selected participants for future knowledge transfer purpose. The video will be edited as a micro-film to be broadcasted to promote the supportive culture of caregivers and volunteers for PWeD or people with MCI. Verbal and written consent will be sought from volunteers involved, caregivers, and PWeD or people with MCI before video capture. Rejection of video shooting did not mean refusal of accepting the intervention. Only those with consent will be shot in the video.

SIGNIFICANCE OF THE STUDY

This study will advance the existing knowledge and provide insights about the implementation strategies in supporting the MWM intervention. The findings will also help to develop educational workshops to promote the application of the intervention in the community.

One of the study aims is to through partnership with the local community centres and involving the volunteers, it is hoped that the intervention can be spread to other centres, other centre users with dementia or their social networks so as to benefit more people. This study can also provide evidence of feasibility of implementing music intervention among PWeD or people with MCI who are not living in nursing home in Hong Kong and Chinese society.

REFERENCES

Alexopoulos, G. S., Abrams, R. C., Young, R. C., & Shamoian, C. A. (1988a). Cornell scale for depression in dementia. *Biological Psychiatry*, 23(3), 271-284.

- Alexopoulos, G. S., Abrams, R. C., Young, R. C., & Shamoian, C. A. (1988b). Use of the Cornell scale in nondemented patients. *Journal of the American Geriatrics Society*, 36(3), 230-236.
- Berntson, G. G., & Cacioppo, J. T. (2004). Heart rate variability: Stress and psychiatric conditions. In M. Malik & A. J. Camm (Eds.), *Dynamic electrocardiography* (pp. 57-64). Oxford, UK: Blackwell Publishing.
- Cahill, S., Pierce, M., Werner, P., Darley, A., & Bobersky, A. (2015). A systematic review of the public's knowledge and understanding of Alzheimer's disease and dementia. *Alzheimer Disease & Associated Disorders*, 29(3), 255-275.
- Carpenter, B. D., Balsis, S., Otilingam, P. G., Hanson, P. K., & Gatz, M. (2009). The Alzheimer's Disease Knowledge Scale: development and psychometric properties. *The Gerontologist*, 49(2), 236-247.
- Cheung, D. S. K., Lai, C. K. Y., Wong, F. K. Y., & Leung, M. C. P. (2018). The effects of the music-with-movement intervention on the cognitive functions of people with moderate dementia: a randomized controlled trial. *Aging Ment Health*, 22(3), 306-315.
- Clary, E. G., Snyder, M., Ridge, R. D., Copeland, J., Stukas, A. A., Haugen, J., & Miene, P. (1998). Understanding and assessing the motivations of volunteers: a functional approach. *Journal of personality and social psychology*, 74(6), 1516.
- Cohen, S., Kamarck, T., & Mermelstein, R. (1983). A global measure of perceived stress. *Journal of health and social behavior*, 385-396.
- Curran, G. M., Bauer, M., Mittman, B., Pyne, J. M., & Stetler, C. (2012). Effectiveness-implementation hybrid designs: Combining elements of clinical effectiveness and implementation research to enhance public health impact. *Medical Care*, 50(3), 217-226.
- Darragh, M., Booth, R. J., Koschwanetz, H. E., Sollers, J., & Broadbent, E. (2013). Expectation and the placebo effect in inflammatory skin reactions: a randomised-controlled trial. *Journal of psychosomatic research*, 74(5), 439-443.
- Galindo-Kuhn, R., & Guzley, R. M. (2002). The volunteer satisfaction index: Construct definition, measurement, development, and validation. *Journal of social service research*, 28(1), 45-68.
- Harmer, B. J., & Orrell, M. (2008). What is meaningful activity for people with dementia living in care homes? A comparison of the views of older people with dementia, staff and family carers. *Aging and Mental health*, 12(5), 548-558.
- Kranjec, J., Beguš, S., Geršak, G., & Drnovšek, J. (2014). Non-contact heart rate and heart rate variability measurements: A review. *Biomedical Signal Processing and Control*, 13, 102-112.
- Krueger, R., & Casey, M. (2015). Participants in a focus group. In R. A. Krueger & M. A. Casey (Eds.), *Focus Groups: A Practical Guide for Applied Research* (5th ed., pp. 77-136). Thousand Oaks, California, USA: SAGE.
- Kwok, T., Lam, K.-C., Yip, A., & Ho, F. (2011). Knowledge of dementia among undergraduates in the health and social care professions in Hong Kong. *Social Work in Mental Health*, 9(4), 287-301.
- Lai, C. K., Lai, D. L., Ho, J. S., Wong, K. K., & Cheung, D. S. (2016). Interdisciplinary collaboration in the use of a music-with-movement intervention to promote the wellbeing of people with dementia and their families: Development of an evidence-based intervention protocol. *Nursing & Health Sciences*, 18(1), 79-84.
- Lawrence, R. H., Tennstedt, S. L., & Assmann, S. F. (1998). Quality of the caregiver-care recipient relationship: Does it offset negative consequences of caregiving for family caregivers? *Psychology and aging*, 13(1), 150.
- Legislative Council of the Hong Kong SAR. (2017). Care services for elderly persons with dementia. Retrieved from <https://www.legco.gov.hk/research-publications/english/essentials-1617ise10-care-services-for-elderly-persons-with-dementia.htm>
- Leung, D. Y., Lam, T.-h., & Chan, S. S. (2010). Three versions of Perceived Stress Scale: validation in a sample of Chinese cardiac patients who smoke. *BMC Public Health*, 10, 513.
- Lin, J.-N., & Wang, J.-J. (2008). Psychometric evaluation of the Chinese version of the Cornell Scale for Depression in Dementia. *Journal of Nursing Research*, 16(3), 202-210.
- Lou, V. W., Lau, B. H.-P., & Cheung, K. S.-L. (2015). Positive aspects of caregiving (PAC): Scale validation among Chinese dementia caregivers (CG). *Archives of Gerontology and Geriatrics*, 60(2), 299-306.
- McDuff, D., Gontarek, S., & Picard, R. (2014). *Remote measurement of cognitive stress via heart rate variability*. Paper presented at the Engineering in Medicine and Biology Society (EMBC), 2014 36th Annual International Conference of the IEEE.
- McParland, P., Devine, P., Innes, A., & Gayle, V. (2012). Dementia knowledge and attitudes of the general public in Northern Ireland: an analysis of national survey data. *International psychogeriatrics*, 24(10), 1600-1613.
- Montedori, A., Bonacini, M. I., Casazza, G., Luchetta, M. L., Duca, P., Cozzolino, F., & Abraha, I. (2011). Modified versus standard intention-to-treat reporting: are there differences in methodological quality, sponsorship, and findings in randomized trials? A cross-sectional study. *Trials*, 12(1), 58.
- Newman, D. B., Tay, L., & Diener, E. (2014). Leisure and subjective well-being: A model of psychological mechanisms as mediating factors. *Journal of Happiness Studies*, 15(3), 555-578.

- O'Connor, M. L., & McFadden, S. H. (2010). Development and psychometric validation of the Dementia Attitudes Scale. *International journal of Alzheimer's disease*, 2010.
- Osman, S. E., Tischler, V., & Schneider, J. (2016). 'Singing for the Brain': A qualitative study exploring the health and well-being benefits of singing for people with dementia and their carers. *Dementia*, 15(6), 1326-1339.
- Peng, R.-C., Zhou, X.-L., Lin, W.-H., & Zhang, Y.-T. (2015). Extraction of heart rate variability from smartphone photoplethysmograms. *Computational and mathematical methods in medicine*, 2015.
- Prince, M., Bryce, R., Albanese, E., Wimo, A., Ribeiro, W., & Ferri, C. P. (2013). The global prevalence of dementia: a systematic review and metaanalysis. *Alzheimer's & dementia: the journal of the Alzheimer's Association*, 9(1), 63-75. e62.
- Reyes del Paso, G. A., Langewitz, W., Mulder, L. J., Roon, A., & Duschek, S. (2013). The utility of low frequency heart rate variability as an index of sympathetic cardiac tone: a review with emphasis on a reanalysis of previous studies. *Psychophysiology*, 50(5), 477-487.
- Roland, K. P., & Chappell, N. L. (2015). Meaningful activity for persons with dementia: Family caregiver perspectives. *American Journal of Alzheimer's Disease & Other Dementias*, 30(6), 559-568.
- Ryan, R. M., Patrick, H., Deci, E. L., & Williams, G. C. (2008). Facilitating health behaviour change and its maintenance: Interventions based on self-determination theory. *European Health Psychologist*, 10(1), 2-5.
- Särkämö, T., Laitinen, S., Numminen, A., Kurki, M., Johnson, J., & Rantanen, P. (2017). Cognitive, emotional and social benefits of regular musical activities in early dementia. *Alzheimer's & dementia: the journal of the Alzheimer's Association*, 13(7), P1209-P1210.
- Shankar, K., Walker, M., Frost, D., & Orrell, M. (1999). The development of a valid and reliable scale for rating anxiety in dementia (RAID). *Aging Ment Health*, 3(1), 39-49.
- Sixsmith, A., & Gibson, G. (2007). Music and the wellbeing of people with dementia. *Ageing & society*, 27(1), 127-145.
- Tarlow, B. J., Wisniewski, S. R., Belle, S. H., Rubert, M., Ory, M. G., & Gallagher-Thompson, D. (2004). Positive aspects of caregiving: Contributions of the REACH project to the development of new measures for Alzheimer's caregiving. *Research on Aging*, 26(4), 429-453.
- Tarvainen, M. P., Niskanen, J.-P., Lipponen, J. A., Ranta-Aho, P. O., & Karjalainen, P. A. (2014). Kubios HRV—heart rate variability analysis software. *Computer methods and programs in biomedicine*, 113(1), 210-220.
- Van't Leven, N., Prick, A.-E. J., Groenewoud, J. G., Roelofs, P. D., de Lange, J., & Pot, A. M. (2013). Dyadic interventions for community-dwelling people with dementia and their family caregivers: a systematic review. *Int Psychogeriatr*, 25(10), 1581-1603.
- van der Steen, J. T., van Soest-Poortvliet, M. C., van der Wouden, J. C., Bruinsma, M. S., Scholten, R. J. P. M., & Vink, A. C. (2017). Music-based therapeutic interventions for people with dementia. *Cochrane Database Syst Rev*(5), CD003477. doi:10.1002/14651858.CD003477.pub3
- Wadham, O., Simpson, J., Rust, J., & Murray, C. (2016). Couples' shared experiences of dementia: a meta-synthesis of the impact upon relationships and couplehood. *Ageing & Mental Health*, 20(5), 463-473.
- Wong, L. P., Chui, W. H., & Kwok, Y. Y. (2011). The volunteer satisfaction index: A validation study in the Chinese cultural context. *Social indicators research*, 104(1), 19-32.
- Woo, B. K. (2013). Knowledge of dementia among Chinese American immigrants. *Asian journal of psychiatry*, 6(4), 351-352.
- Wu, J., Lo, W. T., & Liu, E. S. (2009). Psychometric properties of the volunteer functions inventory with Chinese students. *Journal of Community Psychology*, 37(6), 769-780.
- Xia, N. (2014). *Dementia literacy among nursing students in mainland China: a cross sectional study in three cities*. (Master of Philosophy thesis), The University of Hong Kong, Hong Kong.
- Yu, R., Chau, P. H., McGhee, S. M., Cheung, W. L., Chan, K. C., Cheung, S. H., & Woo, J. (2012). Trends in prevalence and mortality of dementia in elderly Hong Kong population: projections, disease burden, and implications for long-term care. *Int J Alzheimers Dis*, 2012.

Appendix A: Intervention Protocol

Programme feature	Music-with-movement intervention
Eligibility	<p><u>People with MCI/early dementia</u></p> <p>Inclusion criteria:</p> <ol style="list-style-type: none"> Aged 60 or above Cognitively impaired, defined by Global Deterioration Scale 3 or 4 Community-dwelling With stable medical condition Able to communicate in Cantonese have a family caregiver who was willing to take part in the study <p>Exclusion criteria:</p> <ol style="list-style-type: none"> Suffering from any critical medical or psychiatric illnesses Unable to hear even using hearing aids Unable to sit independently for around 30 minutes Received music intervention within six months Participate in any clinical trial within 6 months prior to the start of study <p><u>Caregiver (CG)</u></p> <p>Inclusion criteria:</p> <ol style="list-style-type: none"> Primary caregiver of the PWeD Related to the PWeD and not a paid live-in care attendant <p>Exclusion criteria:</p> <ol style="list-style-type: none"> Suffering from any critical medical or psychiatric illnesses Received music intervention within six months prior to the start of study
Core components	Caregiver will co-design the activities that require them to move their body parts with preferred music. The movement may involve gross- and fine-muscle.
Dose	Recommended to 1 – 3 times per week, for at least 12 weeks, for 30 – 45 minutes each time.
Providers	Trained caregivers will encourage the people with MCI/early dementia to participate in this dyadic intervention.
Sites	Home and Centre
Tailoring	Caregivers are encouraged to discuss with their family member with MCI/early dementia about their music preference and activity preference.
Strategies to improve fidelity	<ol style="list-style-type: none"> Volunteer support; and Peer support during the centre-based music activities

Appendix B: Implementation Strategies

1. To address the objective 1 (PWeD and CG),

Teach families who have relatives with dementia how to deliver the Intervention. Empower them with skills training and continual support offered by centre staff and trained volunteers, with the aim that they will become more likely to sustain its use even after the completion of this Project.

- i. Centre staff and volunteers will provide training to caregivers to deliver the Intervention. The training will be supervised by the project team and music therapist for quality improvement. With the Project Team's past experience, it is important to empower the family caregivers in delivering the Intervention at home, particular in the early stage. Therefore, the 12-week intervention programme is designed with both centre-based and home-based sessions in a 6-month Intervention, while the 13th – 26th weeks will be maintenance period. Centre staff and trained volunteer will provide onsite support to caregivers regularly too. The support in 13th – 26th weeks will be minimal but it will be assessable when centre staff or caregivers consider as necessary.

Week	Mode of delivery	Volunteers home visit
1	Centre-based intervention	
2	Home	√
3	Centre-based intervention	
4	Home	
5	Home	√
6	Home	
7	Centre-based intervention	
8	Home	
9	Home	√
10	Home	
11	Home	
12	Centre	
13 – 26	Home	√ (though it is the maintenance phase and to be monitored by the research team, allowance will be given)

- ii. To foster a closer peer support among the family caregivers in each centre, and for better management by the centre, 7-8 families will be recruited at each cycle. Centre staff can also provide prompt support to them when caregivers have difficulties.
- iii. The caregiver participants will set up support group (can be face-to-face or virtual) to share their caregiving experience and their experience in using music intervention, other than the monthly reinforcement sessions at the Centre.
- iv. The regular meetings may also include other topics such as behavior symptoms management, social services for caregivers and people with dementia in order to maintain the interest of the family caregivers to continue participation.

- v. Caregivers are encouraged to seek help from centre staff and volunteers when they encounter difficulties or problem related to the intervention programme.
- vi. The adherence of the protocol by the caregivers will be co-monitored by the volunteer, centre staffs, and the project manager.

To foster the sense of the ownership of the caregivers to this skill, \$100 will be charged to each dyad as the tuition fee. The charges will be used to cover the expenses in purchasing related music instrument. The music instrument to be used in the intervention will be kept by the participants to encourage them to continue the intervention.

2. To address the objective 2 (Community centre),

Develop certain forms of contractual agreement with NGOs in order to collaborate on:

- (a) *structuring a system for capacity building of the centre staff; and*
- (b) *developing the means to sustain the interest and capacity of families who are members of the participating centres.*
- i. The participating centre will be offered training and accredited as “Music Intervention Centre for People with Dementia and Caregiver” if more than 50% of their activity staffs (e.g. social workers, activity assistants) are trained and assessed to be competent (will be elaborated more); consistently maintain a team of 15 trained older volunteers; and committed to recruit at least 7-8 dyads of PWD and caregivers every three months. Regular remediate training sessions will be offered if there is staff turnover among the participating centres. As the accreditation will need to be renewed every year, if the number of trained staffs and volunteers is lower than the recommended, the Project Team and the centre will discuss the matter to find a mutually acceptable solution.
- ii. A centre will be asked to support and maintain a team of volunteers in order to support the families, and organize centre-based intervention session. This strategy is proposed in order to enhance the sustainability of this programme and can be continued after the project ended.
- iii. A closing ceremony will be launched to acknowledge the contribution of the participating centres. A plaque/certificate will be issues of recognition for display too.

3. To address the objective 2 (Staff members),

Teach centre staff how to deliver the music-with-movement intervention programme (hereafter refer to as the Intervention) and enhanced their abilities to also be teachers of the Intervention, i.e., to teach families how to deliver the Intervention at home as well.

- i. A training programme will be conducted by a music therapist and the Project team, to the staff members of the participating centres. The training programme would include lectures, skill training, return demonstration and discussion. The training package include five training sessions and assessment. For quality assurance, all participating staff members will take part in an assessment to ascertain that the techniques in teaching family caregivers to provide the Intervention and deliver it at home have been mastered. It is assumed that two cycles of training programmes will be offered to cater five participating centres.
- ii. Staff members will be supported during the project period, but the support will be gradually faded out across two implementation cycles. Monthly meetings at the beginning of the project will be arranged for collecting feedback, and solving problems during the implementing the project. After the first round of implementation, quarterly or ad-hoc meetings will be arranged to provide continuous support.
- iii. To acknowledge the participation and competency of individual staff members, they will be certified as “Music Intervention Facilitator” after training and assessment. As the staff members are required to trained

the caregivers and volunteers, their competency will be reviewed during the training by the registered music therapist. Suggestions for improvement will be given.

4. To address the objective 3 and 4 (volunteers),

Build up a mobile voluntary support team with the necessary skills required to enable the caregiver to adopt and sustain the Intervention at home.

- i. High caliber and motivated volunteers will be recruited from the Institute of Active Ageing, PolyU. The project team will match them up with the participating centres according to the living place. The participating centres are welcomed to recruit their volunteers by themselves according to a set of criteria in order to uphold the quality.
- ii. 15 volunteers from each centre will receive training (at centre & at participants' home) to support 7-8 families in each round and if they attain to certain ability (evaluated by music therapist), they will be accredited as "Music Intervention Ambassador". This strategy is also served as a recognition to the contribution and competency of the volunteers, and promote the sense of ownership of this project among them.
- iii. Upon completion of services, volunteers will receive a certificate of appreciation and will be presented in the closing ceremony.
- iv. Two volunteers will be assigned to assist a family which would empower their confidence.
- v. To improve the coherence and communication among volunteers which can also serve as quality assurance and peer support, a What's Apps group will be created to encourage frequent communication among themselves and with the project team. The What's Apps group will be managed by the project assistant and centre-in-charge.
- vi. Allowance (\$60 / half day visit) will be offered to volunteers to cover their travel expenses and as a token of thanks.
- vii. We would expect the volunteers to support the family for six months. In addition to the initial training, four regularly meetings will be organized throughout the six months (2 meetings will be organized by the individual centres, and other 2 meetings will be organized by the project team, that would include all volunteers from different centres to come together). These meetings can serve three purposes: (1) solve the problems of volunteers when they are helping the family at home; (2) increase the sense of coherence among themselves (i.e. peer social support); and (3) provide information in dementia care related topics (i.e. advanced training) to maintain their interest to support this project continuously.
- viii. Volunteers will be invited to provide written feedback (by filling in a simple form, with open- and close-end questions) after each visit, and send to the centre for record. That would help the centre to trace their contribution as well as providing prompt advice.

5. To address the objective 5 (supportive culture),

Create a supportive culture for people with dementia and their families, through learning about and engaging in meaningful interactions during the intervention programme.

- i. With the consent of the dyadic participants and volunteers, video recording will be done during the intervention programme (at home and at centre). The micro film will be produced to highlight the positive interactions between dyads and the dyads with volunteers, which will be broadcasted in the closing ceremony for reducing the stigmatization of dementia in general public and promoting the supportive culture.

- ii. Observations will be made and reports will be documented throughout the project to examine for signs of a changing pattern of relationship and communication between the dyads, as well as between centre volunteers and dyads, over time.
- iii. Observations will be made and reports will be documented to reflect on how the centres support their volunteers and families over time.
- iv. A public seminar will be held to disseminate the results of the projects and the related knowledge about home-based caregiver delivered music intervention.
- v. A professional workshop will be arranged to other health and social care professional.